

# - Exhibit 1 -

**UNITED STATES DISTRICT COURT FOR  
THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

*State of Montana v. Abbott Labs., Inc., et al.,*  
D. Mont. Cause No. CV-02-09-H-DWM

**STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

**(FILED UNDER SEAL)**

substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

Drug	The Sicor Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	\$125.00 <sup>9</sup>	\$100.00	\$25.00	25%
Amikacin Sulfate	\$87.50	\$72.68	\$14.82	20%
Tobramycin Sulfate	\$342.19	\$6.98	\$335.21	4,802%

(P006299-006316).

## 20. TAP

568. TAP engages in an organization-wide and deliberate scheme to inflate AWP's. TAP has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the short-term treatment of duodenal ulcer, erosive esophagitis and gastroesophageal reflux disease

569. The specific drugs manufactured and/or distributed by TAP for which relief is currently sought in this case are set forth below or in Appendix A.

570. TAP controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia.

<sup>9</sup> Calculation based on the AWP listed in the 2000 *Red Book*

571. TAP's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Montana and Montana citizens.

**a. TAP's understanding of AWP and intentional manipulation thereof**

572. According to Criminal Information filed against several doctors and the Indictment filed against six former TAP employees and a urologist, TAP referred its practice of inflating the AWP for Lupron and the corresponding inducement to the physicians as its "Return to Practice" program.

573. At various times, TAP employees would conduct a "Business Review Meeting" with individual doctors or their staff to explain in detail how a doctor could make money by buying Lupron® and exploiting the spread.

574. TAP created sophisticated computer programs, including spreadsheets for use with physicians, to further explain how "Return to Practice" worked and how much money a physician could make from the spread. These computer programs were loaded onto laptop computers used by sales representatives and taken directly into physician's offices.

575. TAP knew and understood that, because Medicare and other insurers relied upon the Publishers to establish AWP's, and because TAP could precisely control the published AWP, TAP could increase whenever they so desired the profit obtained by physicians.

**b. TAP provided other improper incentives**

576. In addition to marketing the spread, TAP has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

577. For example, TAP has pled guilty to illegally conspiring with medical providers to provide free samples which would then be billed to Medicare. In an October 3, 2001, press release that referenced the guilty plea, TAP's president, Thomas Watkins, stated:

We admit that TAP provided free samples of Lupron to a number of physicians, primarily in the early to mid-1990s, with the knowledge that those physicians would seek and receive reimbursement. The billing for free samples is wrong, and it should never have happened.

578. TAP has also provided and/or arranged for many other non-public financial inducements to stimulate the sales of its drugs. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives are designed to lower the cost of the drug to the medical provider while concealing the actual cost.

579. For example, the Indictment alleges three specific instances when TAP employees offered an HMO, a urology practice and a hospital unrestricted "educational grants" of more than \$75,000 to continue their use of Lupron. It offered Tufts HMO \$65,000 in grants.

580. Another way that TAP funneled illicit payments to physicians was through the "TAP into the Future" program, which consisted of providing physicians with all-expense paid weekends at luxurious resorts. These junkets were disguised as educational or consulting programs, with all of the doctors in attendance designated as "consultants" even though the doctors who attended did not do anything that could reasonably be deemed consulting services.

581. As set forth above, TAP's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by the State, Patients and other payors.

**c. TAP has been the target of multiple government investigations**

582. In connection with its scheme to inflate AWP's, TAP has been investigated by the Department of Justice.

583. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP had agreed to pay \$875 million to resolve criminal charges and civil

liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

a. TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

b. TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

c. TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

d. TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

e. Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

f. An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a

urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the “spread” and the “return to practice” program.

The TAP defendants have been sued in a class action in connection with their fraudulent pricing and marketing practices for Lupron®.

584. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

*United States v. TAP Pharm. Prods., Inc.*, No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001).

**d. TAP concealed its AWP manipulation**

585. TAP deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread.

586. For example, TAP instructed physicians not to report the true price they paid for Lupron. According to the Indictment, a TAP Senior Marketing executive, Alan MacKenzie, advised TAP's sales force to:

tell physicians that if doctors disclosed their invoice costs to the Medicare Program, that Program would take steps to reduce the maximum payment allowed for Lupron and thus reduce the physician's profit for Return to Practice.

587. MacKenzie also told the sales force to caution doctors not to discuss their price discounts with other physicians and instructed TAP employees to tell urologists that:

by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCFA then realizes that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amounts you may charge.

588. A presentation to TAP's sales representatives included the same statements listed above, as well as directions for the leader of the presentation, which stated:

The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF/Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.

## 21. Watson

589. Watson engages in an organization-wide and deliberate scheme to inflate AWP's.

Watson has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Ferrlecit	sodium ferric gluconate complex in sucrose injection	Iron Preparation (Blood modifier) Used for treatment of anemia in patients undergoing hemodialysis
InfeD	iron dextran	Iron Preparation (Blood modifier); Nutritional Supplement Used for treatment of iron deficiency
	dexamethasone acetate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema
	dexamethasone sodium phosphate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema
	diazepam	Central Nervous System Agent Used to treat status epilepticus and anxiety disorders. Also used as an anesthetic prior to surgical procedures
	estradiol	Estrogen (Hormone) Used for treatment of menopausal symptoms and postmenopausal osteoporosis
	fluphenazine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
	gemfibrozil	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
	imipramine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used in the treatment of depression
	lorazepam	Central Nervous System Agent Used for treatment of anxiety disorders